Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	*Nothing to declare*	*Nothing new to declare*	*Year of last declaration if nothing new to declare*
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E		X	2012
F		X	1992
G			

(Please mark the appropriate box(es) for each measure with a tick, and fill in the year of last declaration in the last column where applicable.)

Date: Wednesday, April 10, 2019

State Party to the Convention: Germany

Date of ratification/accession to the Convention: Thursday, April 7, 1983

National point of contact:

OR12 - Chemical and Biological Weapons Issues - OR12-RL@diplo.de

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE [2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories [3]

1. Name(s) of facility [4]:
Bernhard-Nocht-Institut für Tropenmedizin

2. Responsible public or private organization or company:
Free and Hanseatic City of Hamburg

3. Location and postal address:
Bernhard-Nocht-Straße 74 D-20359 Hamburg

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

- Free and Hanseatic City of Hamburg
- Federal Ministry of Health
- European Commission
- German Research Foundation

5. Number of maximum containment units [5] within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 4: 100 SqM
BL 4: 50 SqM

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

Diagnosis of and research on viruses causing hemorrhagic fevers (Lassa, Ebola, Marburg, Crimean-Congo hemorrhagic fever). Research includes basic research on virus replication, immunology, and pathogenesis, as well as applied research on therapy and prophylaxis.

1. Name(s) of facility [4]:

Friedrich-Loeffler-Institut (Federal Research Institute for Animal Health)

2. Responsible public or private organization or company:

Federal Ministry of Food and Agriculture

3. Location and postal address:

Südufer 10 D-17493 Greifswald – Insel Riems

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

- Federal Ministry of Food and Agriculture

5. Number of maximum containment units [5] within the research centre and/or laboratory, with an indication of their respective size (SqM):

ABL 3 Ag: 917 SqM
6 laboratories with 287 m2 total work area 18 animal rooms: 8 for cattle (45 m2 each), 4 for pigs and small ruminants (16 m2), 6 for small animals (18 m2 each) one necropsy suite with 98 m2 floor space Facility for highly contagious veterinary viruses of the highest biosafety level (e.g. FMDV, ASFV, PPRV, CSFV): physical treatment of solid and liquid waste and animal carcasses, negative air pressure and double HEPA filters to protect the environment as required by German and international standards; no class III biosafety cabinets or positive-pressure suits, therefore unsuitable for work with human pathogens.
ABL 4: 264 SqM
one laboratory with 146 m2 total work area two animal rooms (66 m2 each) for small or large animals one necropsy room with 26 m2 floor space Facility for zoonotic viruses of the highest biosafety level (e.g. EBOV, HeV, NiV, CCHFV): physical and chemical treatment of solid and liquid waste and animal carcasses, negative air pressure and double HEPA filters to protect the environment as required by German and international standards; positive-pressure suits as personal protective equipment for staff working in the facility.

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

-Diagnosis of and research on animal diseases with and without zoonotic potential
-Veterinary medicine: mechanisms of pathogenesis, vaccines testing, diagnosis of Foot and mouth disease virus (FMDV), Bovine spongiform encephalopathy, African swine fever virus (ASFV), Classical swine fever virus (CSFV), Peste des petits ruminants virus (PPRV), Ebola virus (EBOV), Hendra virus (HeV), Nipah virus (NiV), Crimean-Congo haemorrhagic fever virus (CCHFV) and other animal diseases caused by viruses with and without zoonotic potential

1. Name(s) of facility [4]:

Institut für Virologie der Philipps Universität Marburg

2. Responsible public or private organization or company:

Philipps-University Marburg

3. Location and postal address:

Hans-Meerwein-Strasse 3 D-35043 Marburg

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:

- State of Hessen
- German Research Foundation (Deutsche Forschungsgemeinschaft)
- Federal Ministry of Education and Research
- European Union

5. Number of maximum containment units [5] within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 4: 68.94 SqM
Laboratory
ABL 4: 14.5 SqM
Animal Room
BL 4: 68.94 SqM
Laboratory

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:

Basic research on Marburg virus, Ebola virus, Lassa virus, Nipah Virus, SARS-Corona Virus, Junin Virus and Crimean-Congo Hemorrhagic Fever Virus. Diagnostic services in surveillance of Class 4 - viruses and smallpox virus. Development and characterization of vaccines.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[6] on a State Party's territory:

Biosafety level 3[7]	N/A
Biosafety level 2[8] (if applicable)	N/A

Any additional relevant information as appropriate:

N/A

Part 2 Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

N/A

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Form A, part 2 (ii)

National biological defence research and development programmes

Description

Activities of the Federal Ministry of Health

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The biological defence research and development activities of the Federal Ministry of Health are exclusively conducted at the Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) of the Robert Koch Institute (RKI).
The Robert Koch Institute (RKI) is one of the most important bodies for the safeguarding of public health in Germany. Since its founding in 1891, the Robert Koch Institute has been dedicated to the investigation and prevention of infectious diseases. Today, the institute is also responsible for nationwide health monitoring – the collected data is included in the health reporting of the federal government. Furthermore, the RKI collects and interprets epidemiological data communicated to the institute as a result of the Protection against Infection Act (Infektionsschutzgesetz, IfSG). Its scientists conduct research in infectious disease epidemiology as well as sentinel surveillance projects and support the federal states in outbreak investigations.

The Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) has the mission (1) to identify unusual biological events with highly pathogenic agents that might be used with bioterrorist intent. (2) In addition, ZBS assesses the health implications for the general public and (3) works on preparedness and response for such incidents. This also includes informing decision-makers and professionals on incidents. This also includes informing decision-makers and professionals on incidents and to advise and support them on measures to be taken accordingly. In summary, in managing biological incidents, the centre's tasks include identification, preparedness, information, and response. The centre's work is not limited exclusively to the identification, assessment and handling of possible bioterrorist attacks. Rather the skills already acquired and those to be developed are also used for the investigation of natural outbreaks or those caused by accidents involving special and highly pathogenic agents and toxins.

2. State the total funding for each programme and its source.

Federal Ministry of Health

Total Funding: 8.6 million

Funding Currency: EUR

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

no

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

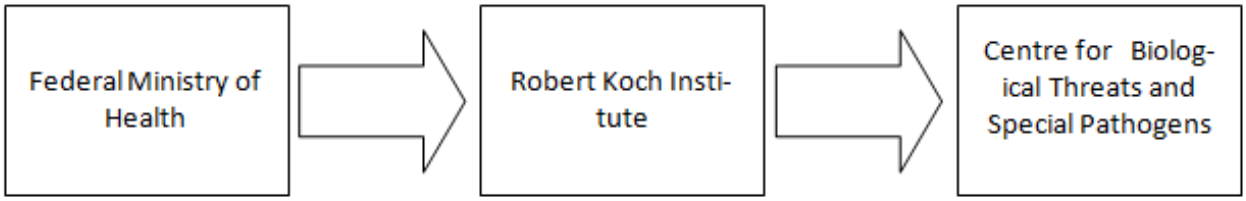
N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

N/A

6. Provide a diagram of the organizaional structure of each programme and the reporting relationships (include individual facilities participating in the programme).

N/A



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Form A, part 2 (iii) is attached for the Centre for Biological Threats and Special Pathogens at the Robert Koch Institute.

Attachments:
N/A

Activities of the Federal Ministry of Defence

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The R&D activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination, and physical protection. Summaries and objectives of all research and development projects in the field of CBRN Medical Defence are accessible online: http://www.bundeswehr.de (in German).

2. State the total funding for each programme and its source.

Federal Ministry of Defence

Total Funding: 9.7 million

Funding Currency: EUR

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

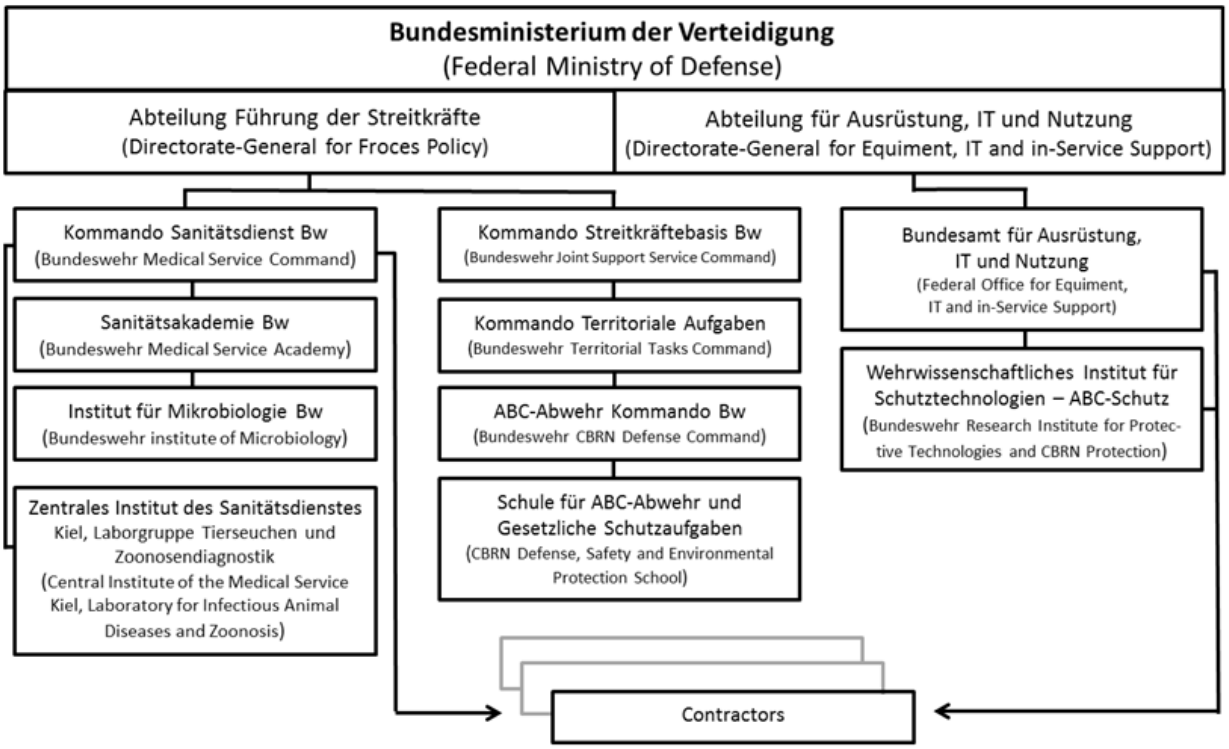
Approx. 1.5 %

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

The objective of the contracted activities is to provide pertinent expertise and hardware to the Federal Ministry of Defence for the improvement of B-defence capabilities. The research areas are the same as mentioned above under #1.

6. Provide a diagram of the organizaional structure of each programme and the reporting relationships (include individual facilities participating in the programme).

N/A



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

4 Forms A, part 2(iii) are attached.

Attachments:

N/A

Activities of the Federal Ministry of the Interior

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

In 2018 the Federal Office of Civil Protection and Disaster Assistance (Bundesamt für Bevölker-ungsschutz und Katastrophenhilfe) has funded the following two research projects:

- Project GranPSA: The objective of this project is to conduct efficacy testing of disinfectants on surfaces of personal protection equipment (PPE) in order to develop decontamination procedures to minimize risks of first responders in case of a biological incident. All investigations are carried out at the Robert Koch Institute, RKI.
- Project NaLaDiba: The objective of this project is to improve diagnostic capabilities and skills of a laboratory network in Germany to detect high-risk pathogens that could be used for bioterrorist attacks. The evaluation of real time PCR assays by a round robin test was conducted. All investigations were carried out at the Robert Koch Institute.

The over-all objective of the Civil Protection Research projects supported and funded by the Federal Office of Civil Protection and Disaster Assistance is to improve preparedness and response to biological threats in order to enhance the protection of the first responders and the population.

2. State the total funding for each programme and its source.

Federal Office of Civil Protection and Disaster Assistance

Total Funding: 0.192 million

Funding Currency: EUR

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

Approx. 100 %

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

Objectives and research areas are the same as described above under #1.

6. Provide a diagram of the organizaional structure of each programme and the reporting relationships (include individual facilities participating in the programme).

The projects GranPSA and NaLaDiBA were conducted by the Robert Koch Institute, Centre for Biological Threats and Special Pathogens (ZBS). For the organisational structure see report of the Robert Koch Institute.

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

See Form A, part 2 (iii) submitted by the Robert Koch Institute.

Attachments:

N/A

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?
Institut für Mikrobiologie der Bundeswehr (Bundeswehr Institute of Microbiology)

2. Where is it located (include both address and geographical location)?
D-80937 München, Neuherbergstraße 11

(48°12` N, 11°34 ` E)

3. Floor area of laboratory areas by containment level:
BL 2: 1258 SqM
BL 3: 67 SqM

Total laboratory floor area (SqM):
1325

4. The organizational structure of each facility.

(i) Total number of personnel: 65

(ii) Division of personnel:
Military: 41
Civilian: 24

(iii) Division of personnel by category:
Scientists: 20
Engineers: N/A
Technicians: 39
Administrative and support staff: 6

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Medicine, veterinary medicine, microbiology, virology, bacteriology, immunology, molecular biology, epidemiology, laboratory medicine

(v) Are contractor staff working in the facility? If so, provide an approximate number.
25

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Federal Ministry of Defence

(vii) What are the funding levels for the following programme areas:

Research: 40% of 7.4 million EUR (total)
Development: 25% of 7.4 million EUR (total)
Test and evaluation: Test and evaluation: 25% of 7.4 million EUR (total) + Education and Training: 10% of 7.4 million EUR (total)

(viii) Briefly describe the publication policy of the facility:

Results are published in scientific journals as well as in reports to the Federal Ministry of Defence and will be presented in national and international scientific meetings.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

1. Aistleitner K, Jeske R, Wölfel R, Wießner A, Kikhney J, Moter A, Stoecker K. (2018). Detection of Coxiella burnetii in heart valve sections by fluorescence in situ hybridization. J Med Micro-biol. Apr;67(4):537-542. doi: 10.1099/jmm.0.000704. Epub 2018 Feb 20.
2. Andersson MO, Marga G, Banu T, Dobler G, Chitimia-Dobler L (2018). Tick-borne pathogens in tick species infesting humans in Sibiu County, Central Romania. Parasitol Res 117(5):1591-1597. doi: 10.107/s00436-018-5848-0.
3. Andersson MO, Radbea G, Frangoulidis F, Tomaso H, Rubel F, Nava S, Chitimia-Dobler L (2018). New records and host associations of the tick Ixodes apronophorus and the first detection of Ehrlichia sp. HF in Romania. Parasitol Res 117: 1285-1289. doi: 10.1007/s00436-018-5800-3.
4. Andersson MO, Tolf C, Tamba P, Stefanache M, Radbea G, Fragoulidis F, Tomaso H, Walden-ström J, Dobler G, Chitimia-Dobler L (2018). Molecular survey of neglected bacterial pathogens reveals an abundant diversity of species and genotypes in ticks collected from animal hosts across Romania. Parasit Vector 11(1):114. doi: 10.1186/s13071-018-2756-1.
5. Balinandi S, Mugisha L, Johnson B, William K, Teddy N, Bakkes DK, Lutwama JJ, Chitimia-Dobler L, Malmberg M. General and local morphological anomalies in Amblyomma lepidum and Rhipicephalus decoloratus infesting cattle in Uganda. J Med Entomol (accepted).
6. Becker BV, Seeger T, Beiert T, Antwerpen MH, Palnek A, Port M, Ullmann R (2018). Impact of Ionizing Radiation on Electrophysiological Behavior of Human-induced Ipsc-derived Cardio-myocytes on Multielectrode Arrays.Health Phys. 2018 Jul;115(1):21-28. doi: 10.1097/HP.0000000000000817.
7. Becker SL, Zange S, Brockmeyer M, Grün U, Halfmann A (2018). Rapid MALDI-TOF-based iden-tification of Brucella melitensis from positive blood culture vials may prevent laboratory-acquired infections. J Hosp Infect. Sep;100(1):117-119. doi: 10.1016/j.jhin.2018.04.008
8. Bestehorn M, Weigold S, Kern WV, Chitimia-Dobler L, Mackenstedt U, Dobler G, Borde J (2018). Phylogenetics of tick-borne encephalitis virus in endemic foci in the upper Rhine re-gion in France and Germany. PLOS One. 13(10):e0204790. doi: 10.1371/journal.pone.0204790.
9. Blitvich BJ, Beaty BJ, Blair CD, Brault AC, Dobler G, Drebot MA, Haddow AD, Kramer LD, LaBeaud AD, Monath TP, Mossel EC, Plante K, Powers AM, Tesh RB, Turell MJ, Vasilakis N, Weaver SC (2018). Bunyavirus Taxonomy: limitations and Misconceptions associated with the current ICTV criteria used for species demarcation. Am J Trop Med. 99(1): 11-16. doi: 10.4269/ajtmh.18-0038.
10. Brockmann SO, Oehme R, Buckenmaier T, Beer M, Jeffery-Smith A, Spannenkrebs M, Haag-Milz S, Wagner-Wiening C, Schlegel C, Fritz J, Zange S, Bestehorn M, Lindau A, Hoffmann D, Tiberi S, Mackenstedt U, Dobler G (2018). A cluster of two human cases of tick-borne encephalitis (TBE) transmitted by unpasteurised goat milk and cheese in Germany, May 2016. Euro Surveill. Apr;23(15). doi: 10.2807/1560-7917.ES.2018.23.15.17-00336.
11. Brugger K, Walter M, Chitimia-Dobler L, Dobler G, Rubel F (2018). Forecasting next season's Ixodes ricinus nymphal density: the example of southern Germany 2018. Exp Appl Acarol 75(3):281-288. doi: 10.1007/s10493-018-0267.
12. Chitimia-Dobler L, Pfeffer T; Dunlop J (2018). Haemaphysalis creatacea a nymph of a new spe-cies of hard tick in Burmese amber. Parasitology 145(5): 1591-1597. doi: 10.1017/s0031182018000537.
13. Chitimia-Dobler L, Rieß R, Kahl O, Wölfel S, Dobler G, Nava S, Estrada-Pena A (2018). Ixodes inopinatus – occurring outside the Mediterranean region. Ticks Tick Borne Dis. 9(2):196-200. doi: 10.1016/j.ttbdis.2017.09.004.
14. Dunlop JA, Selden PA, Pfeffer T, Chitimia-Dobler L (2018). A Burmese amber tick wrapped in spider silk. Cretaceous Res 90:136-141. doi: 10.1016/j.cretres.2018.04.013.
15. Essbauer S, Hofmann M, Kleinemeier C, Wölfel S, Matthee S (2018). Rickettsia diversity in southern Africa: A small mammal perspective. Ticks Tick Borne Dis. 9(2):285-301. doi: 10.1016/j.ttbdis.2017.11.002.
16. Essbauer S, Hofmann M, Kleinemeier C, Wölfel S, Matthee S. (2018). Rickettsia diversity in southern Africa: A small mammal perspective. Ticks Tick Borne Dis. 2018 Feb;9(2):288-301.

17. Fischer S, Spierling NG, Heuser E, Kling C, Schmidt S, Rosenfeld UM, Reil D, Imholt C, Jacob J, Ulrich RG, Essbauer S. (2018). High prevalence of Rickettsia helvetica in wild small mammal populations in Germany. Ticks Tick Borne Dis. 2018 Mar;9(3):500-505.
18. Held J, Schweizer H, Zange S, Panning M, Kern WV, Wagner D (2018). Photo Quiz: Pneumonia and Pyogenic Skin Abscesses in a 79-Year-Old Man. J Clin Microbiol. Jan 24;56(2). pii: e03352-15. doi: 10.1128/JCM.03352-15.
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21. Kalinowski J, Ahrens B, Al-Dilaimi A, Winkler A, Wibberg D, Schleenbecker U, Rückert C, Wölfel R and Grass G (2018) Isolation and whole genome analysis of endospore-forming bacteria from heroin. Forensic Science International: Genetics, 32, 1-6. doi: 10.1016/j.fsigen.2017.10.
22. Kirubakar G, Murugaiyan J, Schaudinn C, Dematheis F, Holland G, Eravci M, Weise C, Roesler U, Lewin A (2018). Proteome Analysis of a M. avium Mutant Exposes a Novel Role of the Bi-functional Protein LysX in the Regulation of Metabolic Activity. J Infect Dis. 2018 Jun 20;218(2):291-299. doi: 10.1093/infdis/jiy100.
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24. Kurhade C, Schreier S, Lee YP, Zegenhagen L, Hjertqvist M, Dobler G, Kröger A, Överby A (2018). Correlation of severity of human tick-borne encephalitis virus disease and pathogenic-ity in mice. Emerg Infect Dis. 24(9): 1709-1712. doi: 10.3201/eid2409.171825.
25. Lienemann T, Beyer W, Pelkola K, Rossow H, Rehn A, Antwerpen MH, Grass G (2018). Geno-typing and phylogenetic placement of Bacillus anthracis isolates from Finland, a country with rare anthrax cases. BMC Microbiol. 2018 Sep 3;18(1):102. doi: 10.1186/s12866-018-1250-4.
26. Lienemann, T, Beyer, W, Pelkola, K, Rossow, H, Rehn, A, Antwerpen, M and Grass, G (2018) Genotyping and phylogenetic placement of Bacillus anthracis isolates from Finland, a country with rare anthrax cases. BMC Microbiol, 18, 102. doi: 10.1186/s12866-018-1250-4
27. Manzulli V, Fasanella A, Parisi A, Serrecchia L, Donatiello A, Rondinone V, Caruso M, Zange S, Tscherne A, Decaro N, Pedarra C, Galante D (2018). Evaluation of in vitro antimicrobial sus-ceptibility of Bacillus anthracis strains isolated during anthrax outbreaks in Italy from 1984 to 2017 J Vet Sci 2018 Dec 4. [Epub ahead of print]
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31. Ruber, J, Geist, J, Hartmann, M, Millard, A.D., Raeder, U., Zubkov, M., Zwirglmaier, K. (2018). Spatio-temporal distribution pattern of the picocyanobacterium Synechococcus in lakes of different trophic states: a comparison of flow cytometry and sequencing approaches. Hydro-biologia, April 2018, Vol 811, Issue 1, pp77-92
32. Sahin M, Buyuk F, Baillie L, Wölfel R, Kotorashvili A, Rehn A, Antwerpen MH, Grass G (2018). The identification of novel single nucleotide polymorphisms to assist in mapping the spread of Bacillus anthracis across the Southern Caucasus. Sci Rep. 2018 Jul 26;8(1):11254. doi: 10.1038/s41598-018-29738-3.
33. Schaumann R, Dallacker-Losensky K, Rosenkranz C, Genzel GH, Stîngu CS, Schellenberger W, Schulz-Stübner S, Rodloff AC, Eschrich K. (2018) Discrimination of Human Pathogen Clostridium Species Especially of the Heterogeneous C. sporogenes and C. botulinum by MALDI-TOF Mass Spectrometry. Curr Microbiol. 2018

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34. Schroll A, Theurl I, Georgi E, Zange S, Rettenbacher T, Bellmann-Weiler R, Weiss G (2018). Newly emerging ulceroglandular tularaemia in Western Austria. Ticks Tick Borne Dis. Jul;9(5):1331-1333. doi: 10.1016/j.ttbdis.2018.06.003.
35. Schroll A, Theurl I, Georgi E, Zange S, Rettenbacher T, Bellmann-Weiler R, Weiss G (2018). Newly emerging ulceroglandular tularaemia in Western Austria. Ticks Tick Borne Dis. 2018 Jul;9(5):1331-1333. doi: 10.1016/j.ttbdis.2018.06.003. Epub 2018 Jun 6.
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37. Springer A, Montenegro VM, Schicht S, Wölfel S, Schaper S, Chitimia-Dobler L, Siebert S, Strube C (2018). Detection of Rickettsia monacensis and Rickettsia amblyommatis in ticks collected from dogs in Costa Rica and Nicaragua. Ticks Tick Borne Dis. 9(6):1565-1572. doi: 10.1016/j.ttbdis.2018.08.002.
38. Springer K, Reuter S, Knüpfer M, Schmauder L, Sänger PA, Felsl A, Fuchs TM (2018): Activity of a Holin-Endolysin System in the Insecticidal Pathogenicity Island of Yersinia enterocolitica. J Bacteriol. 2018 Jul 25;200(16). pii: e00180-18. doi: 10.1128/JB.00180-18. Print 2018 Aug 15.

Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

a. Research, development and evaluation of approaches for the rapid detection, identification, differentiation and typing of Orthopox- , Alpha-, Flavi-, Bunya- and Filoviruses as well as Coxiella, Rickettsia, Burkholderia, Yersinia, Brucella, Bacillus and Francisella spp. using state of the art techniques.

b. Establishment of next generation sequencing techniques, sequence data banks and tools for forensic typing

c. Research, development and evaluation of immunodiagnostics of relevant agents and toxins

d. Studies of the epidemiology, immunopathogenesis and immune response against Francisella tularensis, Bacillus spp., Burkholderia spp., Brucella spp., Yersinia spp., and Flaviviruses

The current programme covers pathogen R I, R II and R III organisms.

No outdoor studies of biological aerosols have been conducted.

1. What is the name of the facility?
Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz (Bundeswehr Research Institute for Protective Technologies and NBC-Protection)

2. Where is it located (include both address and geographical location)?
D-29633 Munster/Oertze, Humboldtstrasse 100, Germany

(53°00` N, 10°08` E)

3. Floor area of laboratory areas by containment level:

BL 2: 520 SqM
BL 3: 360 SqM
stationary laboratories
BL 3: 6 SqM
containment (vehicle bound)

Total laboratory floor area (SqM):
886

4. The organizational structure of each facility.

(i) Total number of personnel: 28

(ii) Division of personnel:
Military: 0
Civilian: 28

(iii) Division of personnel by category:
Scientists: 7
Engineers: 6
Technicians: 15
Administrative and support staff: N/A

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Biology, biochemistry, immunology, molecular biology, bacteriology, mycology, virology, toxicology, toxinology, biotechnology, environmental toxicology, aerosol biology,disinfection, drinking water treatment, waste water treatment, water supply, environmental engineering, mechanical engineering, water microbiology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
3

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

- Federal Ministry of Defence
- EU FP 7 (European Union, Seventh Framework Programme)
- EDA (European Defencse Agency)

(vii) What are the funding levels for the following programme areas:

Research: 40% of 2 million EUR (total)
Development: 30% of 2 million EUR (total)
Test and evaluation: 30% of 2 million EUR (total)

(viii) Briefly describe the publication policy of the facility:

Results will be published in reports to the Federal Office of Equipment, IT and In-Service Support. They will also be presented in public scientific journals and in national and international scientific meetings and symposiums.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Publications in Journals

1. Burke C.W.; Froude J.W.; Miethe S.; Hülseweh B.; Hust M.; Glass P.M., "Human-Like Neu-tralizing Antibodies Protect Mice from Aerosol Exposure with Western Equine Encephalitis Virus", Viruses 2018, Vol. 10, 147
2. Hülseweh B., „Single-chain fragment variable (scFv) with medical potential", Med Res In-nov, 2018, Vol. 2(3), 1-2
3. Tausch, S.-H.; Loka, T.-P.; Schulze, J.-M.; Andrusch, A; Klenner, J.; Dabrowski, P.-W.; Lind-ner M.-S.; Nitsche, A.; Renard B.-Y., „PathoLive - Real time pathogen identification from metagenomic Illumina datasets", Published in bioRxiv 402370; August 2018
4. Andrusch, A.; Dabrowski, P.-W.; Klenner, J.; Tausch, S.-H.; Kohl, C.; Osman, A.-A; Renard B.-Y., Nitsche, A., „PAIPline: pathogen identification in metagenomic and clinical next generation sequencing samples", Published in Bioinformatics Volume 34, Issue 17, Pages i715–i721, September 2018
5. Haverland. F.; Behrens-Gütschow, C.; Köhne S., „Erfolgreiche zivil-militärische Zusam-menarbeit beim Nachweis von schädlichen Bioaerosolen", Pressebeitrag für das Intranet BAAINBw, Februar 2018

Oral Presentations

1. Dawert, T., „Metal-Organic Frameworks for Air Filtration Purposes", Anglo-German Bilat-eral Working Group TA52, 05.06.2018
2. Dawert, T., „Multilayered Filtration Systems with Activated Carbon, Metal-Organic Frameworks and Hopcalite", 4th International Symposium on Development of CBRN Pro-tection Capabilities, DWT, Berlin, 05.09.2018
3. Hagner, K.; Linnenberg, C.; Overkamp, A.; Tandon, R.; Werner, A., „A Future Concept for a Gas-tight NBC Protective Clothing", 4th International Symposium on Development of CBRN Protection Capabilities, DWT, Berlin, 04.09.2018
4. Hesse, F., „System Testing of CBRN Suits with Aerosols", 4th International Symposium on Development of CBRN Protection Capabilities, DWT, Berlin, 04.09.2018
5. Kluge, K., „Cold Atmospheric Plasma for Sensitive Equipment Decontamination", 4th In-ternational Symposium on Development of CBRN Protection Capabilities, DWT, Berlin, Deutschland, 05.09.2018
6. Köhne, S., „Toxin-IED; Lessons learned", Interdisziplinärer Workshop RKI-BND 2018, Berlin, Deutschland, 26.10.2018
7. Köhne, S., „Mobile Laboreinheiten; Sachstand", 47. Sitzung Expertenkreis Labortechnik, Hamburg, Deutschland, 08.11.2018
8. Köhne, S., „Mobile Laboreinheiten; Sachstand", 45. Sitzung Ausschuss für biologische Ar-beitsstoffe (ABAS), Berlin, Deutschland, 04.-05.12.2018
9. Köhne, S., „Toxin-IED; Lessons learned", Fachtagung Bio- und Chemieterrorismus 2018, Berlin, Deutschland, 06.-07.03.2018
10. Köhne, S., „B-Detektion", BWÜ-/CWÜ-Symposium 2018, ZVBw Geilenkirchen, Deutschland, 12.-13.06.2018
11. Moritz, J., „From Lab to Full Size System – Drinking Water from VX Contaminated Raw Water", 32th Anniversary Meeting US/GE Environmental Technology, US Army RDECOM Chemical & Biological Center und BAAINBw, Munster, Deutschland, 14.08.2018
12. Moritz, J.; Fiebing, S.; Reifer, E., „Drinking Water from VX Contaminated Raw Water – From Lab to Full Size Systems", 4th International Symposium on Development of CBRN Protection Capabilities, DWT, Berlin, 04.09.2018
13. Pagel-Wieder, S.; Schache, C.; Rudolph, I.; Klenner, J.; Schirmer, S.; Köhne, S., „Rapid tests for simulants for biological threat agents - new horizons for training", 4th International Symposium on Development of CBRN Protection, DWT, Berlin, Deutschland, 3.-5. Sep-tember 2018
14. Watzelt, T., „Development of Nature Identical Particle Test Water", 32th Anniversary Meeting US/GE Environmental Technology, US Army RDECOM Chemical & Biological Cen-ter und BAAINBw, Munster, Deutschland, 14.08.2018
15. Watzelt, T., „Neue Maßstäbe bei der Bewertung von Vorfiltrationstechnologien", 2. Nati-onaler Workshop „Mobile Wasserversorgung der Bundeswehr", Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz, Husum, Deutschland, 17.10.2018

Posters

1. Berger, M.; Knust I., „Vacuum Decontamination to clean C contaminated exhibits whilst preserving DNA and fingermarks“, 4th International Symposium on Development of CBRN Protection Capabilities, DWT, Berlin, Deutschland, 03. - 05.09.2018
2. Klenner, J.; De Jong, S.; Köhne, S., „Metagenomics Using Nanopore Technology“, 4th In-ternational Symposium on Development of CBRN Protection, DWT, Berlin, Deutschland, 3.-5. September 2018
3. Meißner, T.; Fibinger, M.P.C.; Hülseweh, B., „Core competences of the Biological Labora-tory“, Deutsche Gesellschaft für Wehrtechnik e.V., Berlin, Deutschland, 03-05.09.2018
4. Michel J.; Adam M.; Derakshani N.; Eickmann M.; Eiden M.; Elschner M.; Frangoulidis D.; Groschup M.; Grunow R.; Hörmansdorfer S.; Hülseweh B. et al., „Consolidation of NaLa-DiBA (Nationales Labornetzwerk für die Diagnostik von BT-Agenzien) – Achievements and Tasks for the Future“, Medizinische B-Schutztagung, München, 28.-31.10.2018

Lectures

1. Burzler, M., „ABC-Schutz für militärische Fahrzeuge und Gerät“, Lehrgang Fachgebietsbe-zogene Wehrtechnik – Kraftfahr- und Gerätewesen gtD und htD, BiZBw, Mannheim, Deutschland
2. Moritz, J., „Mobile Wasserver- und -entsorgung“, Laufbahnlehrgang Systemtechnik Land (A/HAT-WT:STLA/SystLand 01/18, 117./118. EGrp.), BiZBw, Mannheim, Deutschland
3. Schache, C.; Grote, G., „Seminar CBRN-Analyseauswertung (Leiter Labor)“, Akademie für Krisenmanagement, Notfallplanung und Zivilschutz (AKNZ), „Bioanalytische Verfahren vor Ort“, GF 220

Bachelor/Master thesis

1. De Jong, S., „Herstellung und Untersuchung von standardisiertem Vergleichsmaterial für nachgehende Metagenomanalysen mittels Next Generation Sequencing (NGS)“, Bachelo-rarbeit, Hochschule Emden/Leer, GF 220, Munster, Oktober 2018
2. Köhne, S., Berufung/Umwandlung des Status Gast in offizielles Mitglied des Expertenkreis Labortechnik (ELATEC), Hamburg, 08.11.2018
3. Zejnullahu, B., „Der Einfluss der Schlauchlänge und Geometrie auf die Ergebnisse bei Ae-rosolmessungen mit optischen Partikelzählern für Untersuchungen zum Testen von Schutzbekleidung“, Praxisarbeit im Rahmen der Laufbahnausbildung htD in der Wehr-verwaltung, WIS GF 410, 07.09.2018

Committee work

1. Dawert, T. NATO Joint CBRN-Capability Development Group Physical Protection Panel, member
2. Haverland, F., „VDI/DIN-Kommission Reinhaltung der Luft (KRdL) – Normenausschuss“
3. Hesse, F., Beiratsmitglied „Bio- und Umwelttechnik“ der Ostfalia Hochschule Wolfenbüttel
4. Hesse, F., NATO Joint CBRN-Capability Development Group Physical Protection Panel, german spokesperson
5. Hülseweh, B., „Nationales Labornetzwerk für Diagnostik von Bioterroristischen Agenzien“ (NaLaDiBa), Forschungsvorhaben des BBK, member
6. Hülseweh, B., Gutachterin für das zivile Sicherheitsforschungsprogramm des BMBF
7. Köhne, S., „Vertreter BMVg im Ausschuss für Biologische Arbeitsstoffe (ABAS)“
8. Köhne, S., „Expertenkreis Labortechnik (ELATEC) im Ausschuss für Biologische Arbeits-stoffe (ABAS)
9. Reifer, E., Executive Management Group (EMG) „Next Generation Personal Protection Garments Against Warfare Agents“ (PRO-SAFE), Defence R&T Joint Investment Programme on CBRN Protection (JIP CBRN) Call 2
10. Kluge, K., DIN-Arbeitsausschuss NA 057-02-03 AA „Desinfektionsmittel Tierhal-tung/Lebensmittelbereich“

Own reports (partly non-public)

1. Auber, S., „Hochsicherheitscontainments in verlegbaren Laboren der Schutzstufe 3 und höher: Belastungsprüfung und Prüfkonzept zur sicheren Inbetriebnahme – Testdokumen-tation und Bewertung“, GF 220, November 2018
2. Hagner, K.; Liebscher, D.; Bagge, C., „Persönliche ABC-Schutzausstattung SpezKr (Teil 1)“, WIS GF 410, 06.08.2018
3. Hagner, K.; Werner, A., „Physiologisches Monitoring zur Gesunderhaltung von Personen beim Tragen von impermeablen Schutzanzügen (Client Acceptance Test)“, WIS GF 410, 28.06.2018
4. Haverland, F.; Köhne, S., Draft Project Arrangement T&E BioDIM Phase 2, T&E BioDIM Phase 2 Consortium, 04.12.2018
5. Hülseweh B., „Toxinaufarbeitung, Charakterisierung und Standardisierung“, WIS AF 110, 01/2018
6. Hülseweh B., „Nachweis neuartiger Infektionserreger“, WIS AF 110, 12/2018
7. Kloth, T.; Behrens-Gütschow, C., Validierung eines H2O2-Begasungsverfahrens zur De-kontamination von im Freiland eingesetztem Material (R1/0000017984-2-T/036/I), GF 220, 11.06.2018
8. Kluge, K., „Plasmadekontamination“, Abschlussbericht R1/0000011755-4-A/051/H, GF 420, Februar 2018
9. Kluge, K., „Evaluierung des Dry-Fog-Systems (DFS) zur Raumdesinfektion als Alternative zur Begasung mit Formaldehyd (Kurz: DryFog)“, Abschlussbericht R1/0000017647-4-A/037/I, WIS GF 420, August 2018
10. Meissner, T., „Sachstandsbericht zum Vorhaben HF066 Verbesserung der B-Kampfstoffanalytik“, WIS AF 110, 09/2018
11. Meissner, T., „Standardisierung biologischer Agenzien“, WIS AF 110, 10/2018
12. Meissner, T.; Fibinger, M. P. C., „Inaktivierung biologischer Agenzien und Auswirkung auf die Analytik“, WIS AF 110, 11/2018
13. Schache, C., Prüfbericht “Testung LFA miPROTECT Simili for Spores“, GF220-13A-2018, 30.08.2018
14. Schache, C., Prüfbericht „Testung LFA miPROTECT Simili for Toxins“, GF220-14A-2018, 19.06.2018
15. Schache, C.; Köhne, S., Auswertungsbeitrag zur Studie „Hochsicherheitscontainments in verlegbaren Laboren der Schutzstufe 3 und höher: Belastungsprüfung und Prüfkonzept zur sicheren Inbetriebnahme“, GF 220, 18.01.2018
16. Schache, C., „Validierung eines H2O2-Begasungsverfahrens zur Dekontamination eines verlegbaren BSL3-Containments im Technologieträger mobile feldfähige Laborinfrastruk-tur (Bio-Yak)“, GF 220, Mai 2018
17. Schache, C., Prüfbericht „Evaluierung neuer Nachweisgeräte für die B-Detektion – MIC Magnetic Induction Cycler“, GF 220-12-2018, 18.04.2018
18. Schirmer, S.; Rudolph, I.; Köhne, S., Auswertungsbeitrag zur Studie „Detektion biologischer Simili-Substanzen“, GF 220, 23.03.2018
19. Watzelt, T., „Partikeltestwasser Teil 2 – Entwicklung“, WIS GF 430, 30.01.2018

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

For these purposes, microbiological safety laboratories of biosafety levels BSL 1- 3 and biosafety
S 1 laboratories for genetically engineered agents are operated, which allow development and research in all areas of B-protection and the investigation of suspect samples in case of CBRN scenarios.
The mission is to close Bundeswehr capability gaps in B-defencse. Development and optimization of the rapid identification/detection of biowarfare agents, development of the elemental basics for the generation and verification of protection factors and both outline and establishment of new and pioneering approaches in decontamination are the primary focus of the biological laboratories and B-detection.

a. Development of early-warning systems permitting non-specific identification of toxins, bacteria and viruses.

b. Optimization of the properties of the available, previously generated detection molecules in their specificity, affinity and avidity for use in the immunological detection and identification systems, which inevitably must be suitable also for field-use. Using new technologies (e.g. development and identification of recombinant antibodies), the repertoire of antibodies and detection molecules for biological agents is constantly expanded.

c. Optimization and automatization of immunological and molecular genetical identification methods.

d. Development, testing and evaluation of equipment and procedures for sampling and rapid and accurate identification of toxins and pathogenic agents in samples from air, water, soil, vegetation (sensor-equipment, collectors, detection kits, automatisation).

e. Sample concentration and preparation incl. inactivation for identification in different matri-ces.

f. Efficient sample processing and risk mitigation method for both ensuring safe handling and preparation of the mixed CBRN samples for the following identification analysis of the CBRN agents. Aim is to develop a set of validated procedures for the separation and preparation of a potential mixture of CBRN agents into distinct C, B, RN aliquots for simultaneous, parallel and/or successive identification analyses, independent of sample matrix, without an impact on each CBRN compound and reducing the turn-around-time for analysis.

g. Stability-tests for B-agents in different matrices.

h. Risk assessment Improvised Explosive Devices (IED) plus B-agents.

i. Development of procedures for disinfection and decontamination.

j. B-Agents and toxin laboratory analysis of suspect samples.

k. Toxin preparation and analytics.

l. Participation in round-robin exercises.

m. Nanotechnology for materials like clothes, paints, etc.

n. Evaluation of B removal efficiency of water treatment equipment.

o. Development and evaluation of mobile equipment for B monitoring of the water supply chain.

The current programme covers non-human/non-animal pathogen biosafety level 1 and pathogenic biosafety level 2 and 3 organisms as well as low-molecular weight toxins.

Outdoor studies were performed for biological aerosols detection and water-purification tests using biowarfare agent simulants like Bacillus atrophaeus, E. coli and phages.

1. What is the name of the facility?

Zentrales Institut des Sanitätsdienstes der Bundeswehr Kiel Laborgruppe Spezielle Tierseuchen- und Zoonosendiagnostik (Central Institute of the Bundeswehr Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis)

2. Where is it located (include both address and geographical location)?

D-24119 Kronshagen, Kopperpahler Allee 120

(54°20´24´´ N, 10°05´37´´ E)

3. Floor area of laboratory areas by containment level:

BL 2: 274 SqM
BL 3: 47 SqM

Total laboratory floor area (SqM):
321

4. The organizational structure of each facility.

(i) Total number of personnel: 7

(ii) Division of personnel:
Military: 3
Civilian: 4

(iii) Division of personnel by category:
Scientists: 3
Engineers: N/A
Technicians: 4
Administrative and support staff: N/A

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Veterinary medicine, microbiology, virology, bacteriology, parasitology, molecular biology, immunology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
N/A

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Federal Ministry of Defence

(vii) What are the funding levels for the following programme areas:

Research: N/A
Development: 10% of 0.139 million EUR (total)
Test and evaluation: Test and evaluation: 25% of 0.139 million EUR (total) + Diagnosis: 55% of 0.139 million EUR (total) + Education and training: 10% of 0.139 million EUR (total)

(viii) Briefly describe the publication policy of the facility:

Results will be published primarily in reports to the Federal Ministry of Defence and in journals for military medicine or technology. Additional presentations occur in public scientific journals as well as national and international scientific meetings and symposiums.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

1. Frickmann H, Köller T, Hagen RM, Ebert KP, Müller M, Wenzel W, Gatzer R, Schotte U, Binder A, Skusa R, Warnke P, Podbielski A, Rückert C, Kreikemeyer B.: Molecular Epide-miology of Multidrug-Resistant Bacteria Isolated from Libyan and Syrian Patients with War Injuries in Two Bundeswehr Hospitals in Germany. Eur J Microbiol Immunol (Bp). 2018 Mar 7;8(1): 1-11
2. Nieter, J, Eimer, C, Frangoulidis, D, Schotte, U: Untersuchungen auf zoonotische Aborter-reger bei Schafen im Raum Prizren (Kosovo). Tagung der DVG-Fachgruppe „Bakteriologie und Mykologie“ 2018, Hannover
3. Smith, B.W., Teifke, J.P., Schotte. U., Greiner, S.T., Chamberlin, S., Buchner, L., Nippgen, M.: Veterinary Interoperability Connects Forces. 64th International Military Veterinary Medical and One Health Symposium 2018, Garmisch-Partenkirchen
4. Fajta, J., Frickmann, H., Schotte, U., Kann, S.: Untersuchung humaner Stuhl- und caniner Kotproben aus ländlichen Gebieten Nordkolumbiens auf bakterielle und parasitäre En-teritiserreger. Tagung der DVG-Fachgruppe „Tropenveterinärmedizin und internationale Tiergesundheit“; Gießen

Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

a. Development and evaluation of diagnostic systems permitting specific identification of microorganisms, parasites, viruses and toxins

b. Development of test kits for use in a deployable containerised field laboratory

c. Diagnosis of zoonoses i.e. Q-Fever, Anthrax, Rabies, Leishmaniasis, Avian Influenza and other Influenza viruses, Hepatitis E-virus, Anaplasma sp., Lumpy Skin Disease E-virus

d. Diagnosis of infectious animal diseases, especially African Swine Fever, Babesiosis, Bovine Viral Diarrhea virus, Border disease virus, Schmallenberg-virus

e. Diagnosis of food and waterborne threats, i.e. Vibrio cholera, Norovirus, Hepatitis E-virus

f. Evaluation of test kits for the detection of Clostridium botulinum toxins and Clostridium perfringens toxins

The current programme covers RG I, II and III organisms.

No outdoor studies of biological aerosols have been conducted.

1. What is the name of the facility?
Schule ABC-Abwehr und Gesetzliche Schutzaufgaben (SABCAbw/GSchAufg) and CBRN Defence, Safety and Environmental Protection School (CDSEP)

2. Where is it located (include both address and geographical location)?
D-87527 Sonthofen/Allgaeu Muehlenweg 12

(47°31’ N, 10°17’ E)

3. Floor area of laboratory areas by containment level:
BL 2: 270 SqM

Total laboratory floor area (SqM):
270

4. The organizational structure of each facility.

(i) Total number of personnel: 12

(ii) Division of personnel:
Military: 9
Civilian: 3

(iii) Division of personnel by category:
Scientists: 3
Engineers: 2
Technicians: 7
Administrative and support staff: N/A

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Medical entomology and parasitology, Toxinology, Microbiology, Molecular biology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
N/A

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Federal Ministry of Defence

(vii) What are the funding levels for the following programme areas:

Research: N/A
Development: Development of methods for detection 30% of 0.08 million EUR. The 0.08 million EUR being the 95 percent share for personnel, consumable items and equipment.
Test and evaluation: Test and evaluation: 20% + Education and training: 50% of 0.08 million EUR. The 0.08 million EUR being the 95 percent share for personnel, consumable items and equipment.

(viii) Briefly describe the publication policy of the facility:

Results will be published primarily in reports to the Office for Military Technology and Pro-curement and to the German Ministry of Defence and will be presented in scientific meetings

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

a. Conceptual development of biological defencce in the Bundeswehr

b. Initiation of and participation in the development of biological defencce material and equipment; drafting of operational requirements

c. Review and establishment of detection methods for pathogens and toxins suitable for military use

d. Development of identification methods for the detection of low molecular toxins

e. Training of NBC defence personnel (theory and practice) including familiarization with the handling of vectors, microorganisms and toxins

f. Training support for non-military government authorities

g. Training support for military personnel of other states

h. Initiation and expert monitoring of studies in the field of biological defencce

i. Drafting of joint publications for biological defencce

The current program covers RG I and II organisms, inactivated material of pathogens RG III and IV, insects and ticks as well as high- and low-molecular toxins; no work has been done with active viruses.

No outdoor studies of biological aerosols have been conducted.

1. What is the name of the facility?

Zentrum für Biologische Gefahren und Spezielle Pathogene (ZBS) at the Robert Koch Institute (RKI) (Centre for Biological Threats and Special Pathogens)

2. Where is it located (include both address and geographical location)?

Nordufer 20, 13353 Berlin, Germany Seestraße 10, 13353 Berlin, Germany

(52°32' N 13°20' E)
(52°32' N 13°20' E)

3. Floor area of laboratory areas by containment level:

BL 2: 5821 SqM
BL 3: 268 SqM
BL 4: 438 SqM

Total laboratory floor area (SqM):

6527

4. The organizational structure of each facility.

(i) Total number of personnel: 144

(ii) Division of personnel:
Military: 0
Civilian: 144

(iii) Division of personnel by category:
Scientists: 86
Engineers: 3
Technicians: 46
Administrative and support staff: 9

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Bacteriology, Biology, Biochemistry, Bioinformatics, Biotechnology, Cell biology, Chemistry, Chemometrics, Genomics, Human biology, Immunology, Laboratory medicine, Medicine, Microbiology, Molecular biology, Molecular medicine, Pharmacology, Prion research, Proteomics, Spectroscopy, Structural biology, Toxicology, Veterinary medicine, Virology, Zoology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

55 of the 144 total staff are contractor staff.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Bernhard Nocht Institute for Tropical Medicine Hamburg, Federal Foreign Office, Federal Ministry for Economic Affairs and Energy, Federal Ministry of Health, Federal Ministry for Education and Research, Federal Office of Civil Protection and Disaster Assistance, German Research Foundation, Society for International Cooperation. European Commission, foreign governmental agencies, non-governmental organisations, Welcome Trust.
There is no funding by the Ministry of Defence.

(vii) What are the funding levels for the following programme areas:

Research: 47,98% of 8.8 million EUR (total)
Development: 36,99% of 8.8 million EUR (total)
Test and evaluation: 15,04% of 8.8 million EUR (total)

(viii) Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in peer reviewed scientific journals as well as present their work at national and international professional meetings.
The Robert Koch Institute signed the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, available at http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/.
Under the Dual Use Regulations of the Robert Koch Institute scientists are required to assess the dual use potential of their research before a project is started, during the project period and before results are published.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references)

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Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

The Centre for Biological Threats and Special Pathogens is divided into a Federal Information Centre for Biological Threats and Special Pathogens (Informationsstelle des Bundes für Biologische Gefahren und Spezielle Pathogene, IBBS) and six departments units (ZBS 1-6). The departmentsThese are briefly described below. More information can be obtained on the RKI homepage: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

The responsibility of the Federal Information Centre for Biological Threats and Special Pathogens (IBBS) is to strengthen national public health preparedness and response capabilities to biological threats caused by highly pathogenic or bioterrorism-related agents ("special pathogens"). IBBS provides support for the public health sector regarding early detection, situation assessment and response to unusual biological incidents related to bioterrorism or any natural occurrence or accidental release of highly pathogenic agents. Key aspects of activity are 1) preparedness and response planning for incidents related to special pathogens, and 2) response to bioterrorism or any unusual biological incident caused by special pathogens. IBBS heads the office of the German “Permanent Working Group of Medical Competence and Treatment Centers Centres for High Consequence Infectious Diseases ” (Ständiger Arbeitskreis der Kompetenz- und Behandlungszentren für hochkontagiöse und lebensbedrohliche Erkrankungen Krankheiten durch hochpathogene Erreger, STAKOB). More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/....

ZBS 1, the Unit for Highly Pathogenic Viruses, is responsible for the establishment of diagnostic methods to detect high-risk pathogens, in particular imported viruses and viruses that could be used for bioterrorist attacks, for the establishment of methods to detect genetically modified viruses, for the development of antigen-based detection methods for risk category 3 pathogens (eventually, risk category 4 pathogens), for the development of rapid and sensitive nucleic acid-based detection methods for the identification, characterisation and differentiation of pathogens of high-risk groups, for the development of strategies for the combat and prevention of infections with highly pathogenic viruses, for research on these pathogens in order to improve both therapy and prophylaxis, for research on mechanisms of pathogenesis of both wild-type viruses and genetically modified viruses that could be used as bioweapons, for the development of SOPs (standard operating procedures) for diagnostics, for the provision of reference samples, standards and materials for diagnostics, for the quality management and further development of detection methods based on serologic or virologic parameters or the pathogen's molecular biology including interlaboratory experiments, and for the organisation of collaborations with European and international high level disease safety laboratories. ZBS1 hosts the Consultant Laboratory for Poxviruses. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

ZBS2, the Unit for Highly Pathogenic Microorganisms, is responsible for the organisation of the diagnostics of samples with bioterrorism suspicion within ZBS, for the development and optimisation of microbiological, molecular biological and immunological detection systems for the identification, characterisation and differentiation of highly pathogenic microorganisms, for the management of a culture collection with highly pathogenic and other relevant microorganisms, for the supply of reference materials for diagnostics of relevant microbial pathogens within the framework of cooperative projects, for quality assurance measures in the field of diagnostics (EMERGE EU-DG SANTE, RefBio UNSGM) for research in the field of epidemiology, pathogenesis and genetics of selected highly pathogenic bacteria with a focus on B. anthracis and F. tularensis, hosting the national Consultant Laboratories for Tularemia and for Bacillus anthracis pathogens, for a Working Group "Cellular interactions of bacterial pathogens" with a focus on F. tularensis and Legionella research , for the development and testing of decontamination and disinfection processes in particular for bioterrorist attacks, and for studies on the evidence and tenacity of highly pathogenic microorganisms under different environmental conditions. For these activities, the unit is running a BSL 3 laboratory. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

ZBS3, the Unit for Biological Toxins, is responsible for the diagnostics of plant and microbial toxins that could be used for bioterrorist attacks using techniques based on cell biological, genetical and serological parameters, as well as chromatographic methods and mass spectroscopy, for the development of SOPs for diagnostics, for the provision of reference samples, reference bacterial strains and standards, and storage of diagnostic material, for the adaptation of the diagnostic materials to the expected sample material, for the development of strategies for the detection of novel and modified toxins and agents, for research on the pathogenesis of the diseases induced, for interlaboratory experiments to assure the quality of diagnostics, for decontamination, for contribution to the development of standard therapies, and for characterisation of adherence/colonisation factors in toxin-producing and tissue-damaging bacteria. Moreover, ZBS3 hosts the national Consultant Laboratory for Neurotoxin-producing Clostridia (botulism, tetanus). More information can be obtained using the following links: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/... http://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/Clostridium_botulinum/... (in German).

ZBS4, the Unit for Advanced Light and Electron Microscopy, is responsible for the rapid diagnostic electron microscopy (EM) of pathogens (primary diagnostics, identification and differentiation of bacterial and viral pathogens in environmental and patient samples), for the morphological characterisation and classification of both novel and rare pathogens by EM, for the development, testing and standardisation of preparation methods for diagnostic EM of pathogens, and for the organisation of an international quality assurance testing scheme and of advanced training courses to preserve and improve quality standards in diagnostic EM, and for light and electron microscopy investigations of pathogens and mechanisms of their infectivity, pathogenicity or tenacity. ZBS4 is the core facility for digital photography, image documentation and for light and electron microscopy at the RKI. It hosts the Consultant Laboratory for Diagnostic Electron Microscopy of Infectious Pathogens. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

ZBS5, the Unit for Biosafety Level 4 Laboratory, is responsible for planning, setting up and later operating a the biosafety level 4 (BSL-4) laboratory within the RKI, for the establishment of diagnostic methods and diagnostic of pathogens in biosafety level 4, for the development of strategies for the prevention, decontamination and control of highly pathogenic viruses together with IBBS and ZBS 1, for the development of decontamination and disinfection measures for BSL-4 pathogens, for investigating the ability of BSL-4 pathogens to survive in biological and environmental samples, and for participation in and organisation of interlaboratory tests for quality assurance of diagnostics (national and international). More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

ZBS6, the Unit for Proteomics and Spectroscopy, is responsible for the characterisation of highly pathogenic microorganisms by means of proteomic techniques (MALDI-TOF mass spectrometry [MS] and LC-MSand ESI-MS, 2D-PAGE) and chem- and bioinformatics, for research on the molecular and structural bases underlying the proteinaceous seeding activity of prions and other self-replicating protein particles ("prionoids") in transmissible and non-transmissible proteinopathies, for proteomics and molecular biology of proteinopathies and neurodegenerative diseases, for the rapid detection of pathogens by vibrational (infrared and Raman) spectroscopy and microspectroscopy, for the development of methods for the characterisation of agents with bioterrorism potential based on confocal Raman microspectroscopy (CRM)surface-enhanced and tip-enhanced Raman spectroscopy (SERS, TERS), and for the characterisation of cells, cell clusters and tissue structures for pathologically and/or chronically degenerative processes by means of microspectroscopic techniques (Raman, IR microspectroscopy and imaginginfrared and MALDI microspectroscopy and imaging) in combination with modern methods of bioinformatics. ZBS6 hosts the Research Group "Prions and Prionoids." and the Research Group "Proteinopathies / Neurodegenerative Diseases". More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...

A list of highly pathogenic biological agents and toxins for which detection methods are established at the RKI can be obtained using the following link: http://www.rki.de/DE/Content/Infekt/Diagnostik_Speziallabore/speziallabo... (in German).
The list contains abrin (Abrus precatorius), Bacillus anthracis, Brucella spp., Burkholderia mallei and pseudomallei, neurotoxin-producing Clostridium spp. (C. baratii, C. botulinum, C. butyricum, C. tetani), Coxiella burnetii, Francisella tularensis, ricin (Ricinus communis), staphylococcal enterotoxins A and B (Staphylococcus aureus), Vibrio cholera, Yersinia pestis, and a number of viruses, e.g. dengue virus, FSME virus, Variola and other pox viruses, Venezuelan equine encephalomyelitis virus, viral haemorrhagic fever viruses, and yellow fever virus. Please note that for several of the agents listed only diagnostics are developed while no research on the pathogen itself is carried out, e.g. smallpox virus.

Outdoor studies of biological aerosols have not been conducted.

Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

> Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

> - When the cause of the outbreak cannot be readily determined or the causative agent [10] is difficult to diagnose,
>
> - When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,
>
> - When the causative agent is exotic to a given geographical region,
>
> - When the disease follows an unusual pattern of development,
>
> - When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
>
> - When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[11]

Epidemiologisches Bulletin

1. Time of cognizance of the outbreak:

Human infectious disease data and public health information are published weekly by the Robert Koch Institute in "Epidemiologisches Bulletin". The Bulletin is available at: http://www.rki.de/DE/Content/Infekt/EpidBull/epid_bull_node.html

No outbreaks of infectious diseases and similar occurrences caused by toxins, that seem to deviate from the normal pattern, were identified.

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication:
N/A

4. Suspected source of disease/intoxication:
N/A

5. Possible causative agent(s):
N/A

6. Main characteristics of systems:
N/A

7. Detailed symptoms, when applicable
N/A

- Respiratory:
N/A

- Circulatory:
N/A

- Neurological/behavioural:
N/A

- Intestinal:
N/A

- Dermatological:
N/A

- Nephrological:
N/A

- Other:
N/A

8. Deviation(s) from the normal pattern as regards

- Type:
N/A

- Development:
N/A

- Place of occurrence:
N/A

- Time of occurrence:

- Symptoms:
N/A

- Virulence pattern:
N/A

- Drug resistance pattern:
N/A

- Agent(s) difficult to diagnose:
N/A

- Presence of unusual vectors:
N/A

- Other:
N/A

9. Approximate number of primary cases:
N/A

10. Approximate number of total cases:
N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken:
N/A

Notes:
N/A

Attachments:
N/A

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

> Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.

2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, inter alia, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.

3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Comments:

Germany encourages scientist and scientific institutions to publish the results of research without any restrictions in scientific journals as well as presenting their work at national and international professional meetings. In sensitive research and development areas scientist and scientific institutions are advised to publish under peer review procedures.
The Robert Koch Institute as well as other German scientific and professional institutions signed the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, available at http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	*Legislation*	*Regulations*	*Other measures*[12]	*Amended since last year*
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	-	-	-	-
(b) Exports of micro-organisms[13] and toxins	-	-	-	-
(c) Imports of micro-organisms[13] and toxins	-	-	-	-
(d) Biosafety[14] and biosecurity[15]	-	-	-	-

Additional information to Form E:

N/A

Confidence-Building Measure "F"

Declaration of past activities in offensive and/or defensive biological research and development programmes

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

Declaration of past activities in offensive and/or defensive biological research and development programmes

1. Date of entry into force of the Convention for the State Party.

Thursday, April 7, 1983

2. Past offensive biological research and development programmes:

- N/A

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

N/A

3. Past defensive biological research and development programmes:

- N/A

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

N/A

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

1. Name of facility:

GlaxoSmith Kline Vaccines GmbH

2. Location (mailing address):

Postfach 1630 D-35006 Marburg

3. General description of the types of diseases covered:

Vaccines contrate production (bulk) against diphtheria, tetanus, rabies, tick-borne encephalitis, mumps are produced in Marburg.
These products are formulated in Marburg. Final vaccines formulation and filling is performed at another GSK site.
Vaccines contrate (bulk) for Meningococcus meningitis serumgroup A is formulated and lyophilised in Marburg.
Final packaging with formulated serumgroups C, W, Y is performed at another GSK site.

1. Name of facility:

Dynavax GmbH

2. Location (mailing address):

Eichsfelder Str. 11 D-40595 Düsseldorf

3. General description of the types of diseases covered:

Hepatitis B (commissioned production, no own licence for marketing)

1. Name of facility:

Vibalogics GmbH

2. Location (mailing address):

Zeppelinstr. 2 D-27472 Cuxhaven

3. General description of the types of diseases covered:

Clinical trial material only, no own licenses for marketing: Tuberculosis vaccine (recombinant and non-recombinant), Smallpox vaccine (recombinant), Ebola vaccine (recombinant), Bordetella vaccine, HIV vaccine (recombinant), Zika vaccine (recombinant), Typhus vaccine, RSV, Newcastle Disease Virus (Drug Substance, recombinant), Influenza A (PR8 vaccine).

1. Name of facility:

IDT Biologika GmbH

2. Location (mailing address):

Postfach 400214 D-06861 Dessau-Roßlau

3. General description of the types of diseases covered:

Live Smallpox vaccines, Following Investigational Medicinal Products - live recombinant HIV vaccines, live recombinant Malaria vaccines, live recombinant and inactivated recombinant Filovirus vaccines, live recombinant Flavivirus vaccines, MERS-CoV vaccines, inactivated recombinant Lassa virus vaccine

1. Name of facility:

GlaxoSmithKline Biologicals (Branch of SB Pharma GmbH & Co KG)

2. Location (mailing address):

Zirkusstr. 40 D-01069 Dresden

3. General description of the types of diseases covered:

Influenza virus vaccine for human immunisation purposes

1. Name of facility:

Burgwedel Biotech GmbH (MSD Group)

2. Location (mailing address):

Im Langen Felde 5, D-30938 Burgwedel

3. General description of the types of diseases covered:

expected to be approved this year for manufacture of live recombinant Ebola virus vaccines
(GMP inspection pending)

Notes

1. World Health Organization

2. World Organization for Animal Health.

3. The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

4. For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

5. In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

6. Microorganisms pathogenic to humans and/or animals

7. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

8. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

9. Including viruses and prions.

10. It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

11. See paragraph 2 of the chapeau to Confidence-Building Measure B.

12. Including guidelines.

13. Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

14. In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

15. In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.